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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,980	03/31/2004	Edward Wells Knowlton	KNW-0018	5920
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Goodwin Procter LLP Attn: Patent Administrator 135 Commonwealth Drive Menlo Park, CA 94025-1105			EXAMINER IWAMAYE, ANDREW MICHAEL	
			ART UNIT	PAPER NUMBER
			3774	
			NOTIFICATION DATE	DELIVERY MODE
			02/17/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/813,980

Applicant(s)

KNOWLTON, EDWARD WELLS

Examiner

ANDREW IWAMAYE

Art Unit

3774

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 15-24 and 26-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 15-24, 26-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-945)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/08/2010 has been entered.

Response to Arguments

2. Applicant's arguments, filed 07/09/2010, with respect to the 35 USC 112, second paragraph rejection have been fully considered and are persuasive. The previous 35 USC 112, second paragraph rejection has been withdrawn.
3. Applicant's arguments with respect to the prior art rejections of **claims 1-7, 15-24, and 26-43** have been considered but are moot in view of the new ground(s) of rejection. Upon further review of the Knowlton reference, Examiner has set forth new rejections of all of the claims.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claim 43** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 43 contains the trademark/trade name Steri-strip™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe an adhesive strip and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 1-7, 15-24, 26, 30-40, and 42-43** are rejected under 35 U.S.C. 102(b) as being anticipated by Knowlton (US 6,350,276 B1).

Regarding **claim 1**, Knowlton teaches a **method of energetically treating a target tissue site, the method comprising:**

orienting/pre-positioning tissue at the site of treatment into an aesthetically corrected configuration via a mechanical force applied by a device, for example, a template 12 (see Figures and col. 8, ll. 11-30);

wherein orienting of the selected tissues is used to reduce the resting skin tension of the treatment site and create a directed wound healing response so as to

create or facilitate the shaping of a thermal lesion (see for example, Figures 7-9 and col. 12, ll. 1-49, which clearly show that when the template 12 compresses tissue, converging force vectors are applied to troughs of a treatment site, thereby contracting/reducing the resting skin tension of the troughs of treatment site and smoothing out the surface morphology of the treatment site);

delivering energy to the tissue site using the device (i.e. **an energy delivery device**) in order to disrupt and/or cleave molecular bonds within the collagen matrix of the tissue (see for example, Figures and col. 8, ll. 11-30, for example);

securing tissue in the aesthetically corrected and contracted configuration by allowing the collagen of the tissue to reform bonds (i.e. **remodel**) while the tissue is being contracted (i.e. **producing a thermal adhesion or lesion at the tissue site and remodeling at least a portion of tissue at the tissue site**) (see for example, col. 8, line 51 to col. 11, line 64) .

Regarding **claim 2**, in some embodiments, Knowlton teaches for the energy delivery device and template to be separate (see for example, col. 4, ll. 44-54; col. 13, ll. 18-32; and ll. 48-50). In some embodiments, Knowlton teaches for the energy delivery device to be separate from a conductive garment that orients tissue at the treatment site into an aesthetically corrected configuration. Thus, in these embodiments, Knowlton teaches orienting tissue into an aesthetically corrected configuration by first placing a garment on the patient and then applying energy to the garment and tissue with a handheld energy delivery device (see for example, col. 14, ll. 55+ and Figures 11-12b).

Regarding **claim 3**, Knowlton teaches the tissue to be oriented by placing a garment over the treatment site, thereby causing the tissue to assume a desired three-dimensional figure (i.e. the tissue is oriented by dependant positioning of the patient's tissue (i.e. the patient)) (see for example, Figures 11-12b).

Regarding **claims 4-5**, it is the Examiner's position that upon the application of heat and pressure to the continuous piece of tissue as shown in Figures 7-9, a substantially continuous area of a plurality of collagen fibrils is affected (i.e. a substantially continuous plurality of thermal adhesions/lesions are produced in the plurality of collagen fibrils).

Regarding **claims 6-7**, in the embodiments wherein energy is applied via a garment, as shown in Figures 11-12B, energy is delivered in a selected/grid pattern to produce a substantially uniform thermal adhesion/lesion. In the alternative, Knowlton teaches pulsed modes/patterns of application (see for example, col. 6, ll. 23-26), and delivering mechanical energy in specific profiles (see for example, col. 19, ll. 1-19).

Regarding **claim 15**, Knowlton teaches cooling a layer of tissue of at least a portion of the tissue site via a cooling device 13 (see for example, Figures and col. 4, ll. 55+).

Regarding **claim 16**, Knowlton teaches producing a reverse thermal gradient 25 within at least a portion of the tissue site (see for example, Figures and col. 5, ll. 51-59).

Regarding **claim 17**, Knowlton teaches the application of heat to reach all layers of the skin as well as underlying tissue underneath the skin (see for example, col. 5, ll. 52-59).

Regarding **claim 18**, Knowlton teaches producing at least one of a wound healing response or scar collagen induction within the tissue site (see for example, col. 11, ll. 40-54 and col. 14, ll. 9-54).

Regarding **claim 19**, in the method of Knowlton, the skin tissue is not completely ablated. As such, in the method of Knowlton, at least a portion of a surface, a tissue layer, or an epidermal layer at or adjacent the tissue site is substantially preserved.

Regarding **claims 20-22 and 24**, as set forth in the rejections supra, Knowlton teaches contracting/tightening/rejuvenating/reshaping tissue.

Regarding **claim 23**, Knowlton teaches the disclosed application of heat/energy to increase elasticity of at least a portion of the tissue site (see for example, col. 14, ll. 18-36).

Regarding **claim 26**, as set forth in the rejections supra, Knowlton teaches the portion of tissue to be one of a collagen matrix or a subjacent collagen matrix.

Regarding **claim 30**, as set forth supra, Knowlton teaches the claimed method. Knowlton further teaches using a feedback control system 54 and sensors 23 that measure temperature of the patient's tissue (i.e. **patient feedback**) to control the delivery of energy to the

tissue and reduce the risk of cell necrosis (col. 8, ll. 31-50). As such, Knowlton teaches **using patient feedback to titrate the delivery of energy to the treatment site.**

Regarding **claim 31**, as set forth supra, Knowlton teaches the method substantially as claimed. The applications of thermal energy and mechanical energy in the method of Knowlton are substantially overlapping, as claimed, since the tissue being compressed (i.e. mechanical energy) is also being heated (i.e. thermal energy). Moreover, the simultaneous application of mechanical energy and thermal energy minimizes aesthetic discontinuities or irregularities in the remodeled portion, as the mechanical energy prevents the tissue from remodeling back to its original, untightened position.

Regarding **claim 32**, as set forth supra in the rejection of claim 18 supra, Knowlton teaches producing at least one of a wound healing response or scar collagen induction within the tissue site.

Regarding **claim 33**, as shown in Figures 7-9, Knowlton teaches delivering a vectored mechanical force to the tissue site to correct an aesthetic deformity, secure tissue or create a directed wound healing response.

Regarding **claim 34**, as set forth supra in the rejection of claim 16 supra, Knowlton teaches producing a reverse thermal gradient within at least a portion of the tissue site.

Regarding **claims 35-36**, Knowlton teaches performing a time sequence of energetic treatments wherein a subsequent thermal dose is delivered in a period of days or weeks after

the initial dose in order to augment, improve, or enhance the tissue remodeling. (see for example, col. 11, ll. 39-54).

Regarding **claim 37**, Knowlton teaches selecting treatment sites based on surface deformities such as wrinkles, scars, and skin deformities (see for example col. 12, ll. 1-49). As shown in Figures 7-9, the tissue site is selected based on an amount of peaks/valleys (i.e. convexity) at the tissue site.

Regarding **claims 38-40** and **42-43**, as set forth supra, Knowlton teaches each of the claimed steps. Refer to rejections as set forth supra. In the method of Knowlton, thermal energy delivery to the substantially non-convex areas adjacent to convex areas is minimized since Knowlton teaches using a cooling device that reduces thermal damage of the skin surface.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. **Claims 27-29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Knowlton (US 6,350,276 B1) alone.

Regarding **claims 27 and 29**, as set forth supra, Knowlton teaches the method substantially as claimed, but fails to explicitly teach performing a liposuction procedure substantially at the tissue site.

However, Knowlton does teach that it was well known in the art at the time of the invention that liposuction causes looseness in skin, which later requires a skin tightening procedure (see col. 1, line 54 to col. 2, line 5).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the skin-tightening method of Knowlton by performing it over a portion of tissue that has previously underwent liposuction in order to rejuvenate the skin and render it more aesthetically pleasing without major surgical intervention.

Regarding **claim 28**, the method of Knowlton appears to be identical to that claimed and disclosed in the instant application. As such, it is the Examiner's position that the method of Knowlton comprises skeletonizing at least a portion of fibrous septae at the tissue site, as claimed (see also col. 2, ll. 6-17).

11. **Claim 41** is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Knowlton (US 6,350,276 B1).

Regarding **claim 41**, as set forth supra, Knowlton teaches the method substantially as claimed. Knowlton anticipates and completely envisages the range from about 0.1 to 10 lbs by having a range greater than zero, which overlaps the claimed range.

If not taught by Knowlton, it would have been obvious to one having ordinary skill in the art to modify the method of Knowlton by applying a force within the claimed range in order to provide a force that sufficiently smoothes the skin in the desired aesthetic configuration.

Applicant has not disclosed that having a force in the claimed range solves any stated problem or is for any particular purpose. Moreover, it appears that the method would perform equally well with any positive force up to the point of tissue destruction/injury. Accordingly, it would have also been obvious to one having ordinary skill in the art at the time of the invention to utilize the claimed range because such a modification is a mere design consideration which fails to patentably distinguish over the prior art of Knowlton.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW IWAMAYE whose telephone number is (571)270-7036. The examiner can normally be reached on Monday-Friday 7:30AM-5:00PM, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571)272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. I./

/DAVID ISABELLA/

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Examiner, Art Unit 3774
02/11/2011

Supervisory Patent Examiner, Art Unit
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